K100767

APR - 5 2011

April 4, 2011

510(k) Summary (revised)

Submitted by:	Church & Dwight, Co. Inc. 469 North Harrison Street Princeton, NJ 08543
Contact Person:	Joseph Ciccone Manager, Regulatory Affairs (609) 497-7251
Date Prepared:	March 17, 2010
Proprietary Name:	TROJAN SUPRA® Lubricated Polyurethane Male Condom
Common Name:	Polyurethane Condom
Classification Name:	Condom [21 CFR §884.5300]
Predicate Device:	TROJAN-ENZ® Brand Lubricated Latex Male Condom Pre-1976

Description of Device: The TROJAN SUPRA® Lubricated Polyurethane Condom is a male condom consisting of a sheath of polyurethane with a lubricated coating. The condom is a straight-walled, non-textured, nipple-end condom with a nominal length of 190 mm and an nominal flat-width of 58 mm.

Intended Use of the Device: The 510(k)-subject condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes (intended to prevent pregnancy, HIV/AIDS, and other sexually transmitted infections, STIs).

Technological Characteristics: There is no difference in the basic technological characteristics of the 510(k)-subject condom and the predicate condom. Both the 510(k)-subject condom and the predicate condom are of the same basic design, both are straight-walled, nipple-ended, lubricated condoms with an integral formed ring at the open-end. The 510(k)-subject condom differs from the predicate condom in the material used to manufacture each condom: the predicate condom is made from natural rubber latex, the 510(k)-subject condom made from a polyurethane resin. With minor exceptions, the labeling for the 510(k)-subject device is the same as the predicate device. Exceptions to the predicate device labeling include: country of origin, the 510(k)-subject condom will be made in Japan; and absence of natural rubber latex warning for latex sensitive users, unlike the predicate device, the 510(k) subject device does not contain natural rubber.

lubricant type for 60 minutes at 37°C. Compatibility was assessed at three different aging conditions. Changes in airburst and tensile properties were evaluated compared to a control (subject condom conditioned but with no additional lubricant). The results of testing demonstrated that the subject condom is not compatible with any lubricant type. The subject condom is labeled accordingly.

Summary of Studies

Pre-Clinical Safety Studies – Safety information regarding the compound materials and finished products (e.g., chemical degradation studies) was provided and raised no safety concerns. Biocompatibility studies on the non-lubricated condom and on the lubricated finished product include *in vitro* cytotoxicity extract test and direct contact test; sensitization test; vaginal irritation test; acute systemic toxicity; penile irritation test; 90-day muscle implantation study; bacterial reverse mutation assay; mouse lymphoma assay; and *in vitro* chromosomal aberration study.

Clinical In-Use Slip/Break Study – A slippage and breakage study following a protocol prepared to meet the FDA guidance: "Clinical Testing Guidance for New Material Male Condoms," was conducted using the 510(k)-subject condom with a standard latex condom serving as control. Over 290 couples were included in the study, the clinical breakage rate for the polyurethane condom was 1.1% compared to 0.9% for the control. The clinical slippage rate was 2.0% for the polyurethane and 1.0% for the control. The polyurethane condom was statistically no different from the control latex condom in both clinical breakage and slippage rate.

Physical testing data – Followed the FDA guidance: "Clinical Testing Guidance for New Material Male Condoms" and included the testing of three (3) lots of the 510(k)-subject condom. Testing included tensile strength, force at break, and elongation and air burst volume and air burst pressure were performed according to ASTM D 6324-08, and water leakage tests were carried out for the same lots in accordance with testing procedure of ISO 4074 (AQL = 0.25). In addition, condoms were tested for tear resistance and propagation according to ASTM D 624-00 ("Standard Test Methods for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers"). Further testing to simulate in-use conditions by performing tensile strength, force at break, and elongation at 37° C, 50% Relative Humidity were completed according to ASTM D 6324-08. The results of physical testing support the performance effectiveness of the 510(k) product.

Package integrity – An evaluation of seal integrity was performed on three lots (3) of the 510(k)-subject device according to ASTM D 6324-08 with satisfactory results.

Barrier Properties/Permeability: Viral Penetration Study – Was performed on three (3) test lots of the 510(k)-subject polyurethane condom and one lot of the commercially available predicate device. Results of testing on a fourth lot of the 510(k)-subject device were submitted at the request of FDA to confirm the prior testing. The cumulative results of the studies demonstrate the barrier effectiveness of the 510(k) device to viral penetration under conditions of the *in vitro* study.

Shelf-life – Stability of the 510(k)-subject device was established from results of physical testing data using a protocol that followed 21 CFR 801.435 as a guide. Based on the evaluation of the results of the physical testing data, the expiring date has been set at 60 months.

Lubricant Compatibility – The subject condom was evaluated for compatibility with water-based, silicone oil-based, and glycol-based personal lubricants. Condom samples were exposed to two brands of each

(*continued...*)

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Mr. Joseph Ciccone
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APR - 5 2011

Re: K100767
Trade Name: TROJAN SUPRA® Lubricated Polyurethane Male Condom
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MOL
Dated: March 23, 2011
Received: March 23, 2011

Dear Mr. Ciccone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K100767

Device Name: TROJAN SUPRA® Lubricated Polyurethane Male Condom

Indications for Use: The TROJAN SUPRA® Lubricated Polyurethane Male Condom is used for contraception and for prophylactic purposes (to help reduce the risk of pregnancy and the transmission of sexually transmitted infections, STIs).

Prescription Use _____ OR Over-the-Counter Use X

(Per 21 CFR §8001.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100767

TROJAN BRAND CONDOMS

CHURCH & DWIGHT CO., INC.